



**[BILLING CODE: 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Biomedical Imaging and Bioengineering (NIBIB)**

**Announcement of Requirements and Registration for the 2015 Design by**

**Biomedical Undergraduate Teams (DEBUT) Challenge**

**Authority:** 15 U.S.C. 3719

**SUMMARY:** The National Institute of Biomedical Imaging and Bioengineering (NIBIB) Design by Biomedical Undergraduate Teams (DEBUT) Challenge is open to teams of undergraduate students working on projects that develop innovative solutions to unmet health and clinical problems. NIBIB's mission is to improve health by leading the development and accelerating the application of biomedical technologies. The goals of the DEBUT Challenge are to provide undergraduate students valuable experiences such as working in teams, identifying unmet clinical needs, and designing, building and debugging solutions for such open-ended problems; to generate novel, innovative tools to improve healthcare, consistent with NIBIB's purpose to support research, training, the dissemination of health information, and other programs with respect to biomedical imaging and engineering and associated technologies and modalities with biomedical

applications; and to highlight and acknowledge the contributions and accomplishments of undergraduate students.

**DATES:** The competition begins [ INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Submission Period: March 1, 2016 to May 30 2016, 11:59 PM EDT

Judging Period: June 6, 2016 to August 5, 2016

Winners announced: August 22, 2016

Award ceremony: October 2016, Biomedical Engineering Society  
Conference, Minneapolis, Minnesota

**ADDRESSES:** To submit entries, visit <http://www.nibib.nih.gov/training-careers/undergraduate-graduate/design-biomedical-undergraduate-teams-debut-challenge/> or <http://venturewell.org/students/debut>.

**FOR FURTHER INFORMATION CONTACT:** [info@nibib.nih.gov](mailto:info@nibib.nih.gov) or (301) 451-4792.

**SUPPLEMENTARY INFORMATION:**

**Subject of Challenge:** NIBIB's mission is to improve health by leading the development and accelerating the application of biomedical technologies. By challenging undergraduate students to identify unmet clinical needs and develop innovative solutions for them, NIBIB targets the education of biomedical engineers who have the background,

skills, and confidence to make outstanding contributions to biomedical technologies.

Engaging undergraduate students to work in teams to design, build and debug solutions to real-world problems/needs in healthcare, not only prepares them to function effectively in their future work environment, but also yields novel, innovative biomedical tools that can transform healthcare.

The NIBIB DEBUT Challenge solicits design projects that develop innovative solutions to unmet health and clinical problems. Areas of interest for the biomedical engineering projects include, but are not limited to: diagnostics, therapeutics, technologies for underserved populations and low resource settings, point-of-care systems, precision medicine, preventive medicine, and technologies to aid individuals with disabilities. Student Teams participating in capstone design projects are especially encouraged to enter the challenge.

To support and expand the DEBUT Challenge, the NIBIB has joined forces with VentureWell, a not-for-profit leader in funding, training, coaching and early investment that brings student innovations to market. In past years, undergraduate student teams have applied separately to NIBIB's DEBUT Challenge and to VentureWell's BMESStart competition. The new public-private partnership on DEBUT, allows student teams to submit one application and gives teams more chances to win a prize in recognition of their technology solution. Student Teams entering the Challenge will have the option to have their entries also considered for prizes offered by VentureWell. VentureWell prizes will be selected and awarded by VentureWell following a separate judging process. The rules for the VentureWell prizes and the additional submission components that are

required to compete for them can be found at

<http://venturewell.org/students/debut/guidelines>.

**Rules for Participating in the Challenge:**

- 1) To be eligible to win a prize under this Challenge, an individual must be a member of a “Student Team” as described below, and each individual of a “Student Team”:
  - a) Must be an undergraduate student enrolled full-time in an undergraduate curriculum during at least one full semester (or quarter if the institution is on a quarter system) of the 2015-2016 academic year;
  - b) Must form or join a “Student Team” with at least two other individuals for the purpose of developing an entry for submission to this challenge. Each student on the Student Team must satisfy all the requirements for competing in this challenge. While at least one Student on the Team must be from a biomedical engineering or bioengineering department (*i.e.*, majoring in biomedical engineering or bioengineering) , interdisciplinary teams including students from other fields are welcome and encouraged;
  - c) Shall be a citizen or permanent resident of the United States. Foreign students who are studying in the United States on a visa are eligible to be part of the competing Student Teams. However, they will not receive a monetary prize if they are part of a winning Student Team. See Prize section below for the distribution of prizes. As acknowledgement of their participation, however, the names of foreign students who are part of winning Student Teams will be

listed among the winning team members when results are announced and at the award ceremony.

- d) Must be a member of only one Student Team:
- e) Must be 13 years of age or older. Individuals who are younger than 18 must have their parent or legal guardian complete the [Parental Consent Form](https://www.nibib.nih.gov/sites/default/files/Parental%20Consent%20Form.pdf) found at <https://www.nibib.nih.gov/sites/default/files/Parental%20Consent%20Form.pdf>
- f) Shall have agreed to be registered by the Team Captain (selected by the Student Team) to participate in the Challenge under the rules promulgated by the NIH as published in this Notice;
- g) Shall have complied with all the requirements set forth in this Notice;
- h) May not be a Federal entity;
- i) May not be a Federal employee acting within the scope of the employee's employment and further, in the case of HHS employees, may not work on their submission(s) during assigned duty hours;
- j) May not be an employee of the NIH, a judge of the challenge, or any other party involved with the design, production, execution, or distribution of the Challenge or the immediate family of such a party (i.e., spouse, parent, step-parent, child, or step-child); and
- k) Must acknowledge understanding and acceptance of the DEBUT challenge rules by signing the NIBIB DEBUT Challenge Certification Form found at <https://www.nibib.nih.gov/sites/default/files/NIBIB%20DEBUT%20Certification%20Form.pdf>

[ion%20Form.pdf](#). Each entry must include one NIBIB DEBUT Challenge Certification Form, completed with: the printed names of Student Team members, an indication of whether the team member is either a US citizen or permanent resident (as opposed to a foreign student on a visa), and be signed and dated by each individual member of the Student Team. Entries that do not provide a complete Certification Form will be disqualified from the challenge;

(2) Each entry into this challenge must have been conceived, designed, and implemented by the Student Team without any significant contribution from other individuals

(3) Federal grantees may not use Federal funds to develop their Challenge submissions unless use of such funds is consistent with the purpose of their grant award and specifically requested to do so due to the Challenge design, and as announced in the Federal Register.

(4) Federal contractors may not use Federal funds from a contract to develop their Challenge submissions or to fund efforts in support of their Challenge submission.

(5) Submissions must not infringe upon any copyright or any other rights of any third party.

(6) By participating in this Challenge, each individual and entity agrees to assume any and all risks and waive claims against the Federal government and its related entities (as defined in the COMPETES Act), except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from participation in this Challenge, whether the injury, death, damage, or loss arises through negligence or otherwise.

(7) Based on the subject matter of the Challenge, the type of work that it will possibly require, as well as an analysis of the likelihood of any claims for death, bodily injury, property damage, or loss potentially resulting from Challenge participation, no individual participating in the Challenge is required to obtain liability insurance or demonstrate financial responsibility in order to participate in this Challenge.

(8) By participating in this Challenge, each individual agrees to indemnify the Federal government against third party claims for damages arising from or related to Challenge activities.

(9) An individual shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during the Challenge if the facilities and employees are made available to all individuals and entities participating in the Challenge on an equitable basis.

(10) By participating in this challenge, such individuals grant to NIBIB an irrevocable, paid-up, royalty-free, nonexclusive worldwide license to post, link to, share, and display publicly the entry on the Web, newsletters or pamphlets, and other information products. It is the responsibility of the individuals on the Student Team to obtain any rights necessary to use, disclose, or reproduce any intellectual property owned by third parties and incorporated in the entry for all anticipated uses of the entry.

(11) NIH reserves the right, in its sole discretion, to (a) cancel, suspend, or modify the Challenge, and/or (b) not award any prizes if no entries are deemed worthy.

(12) Each individual agrees to follow all applicable federal, state, and local laws, regulations, and policies.

(13) Each individual participating in this Challenge must comply with all terms and conditions of these rules, and participation in this Challenge constitutes each such participant's full and unconditional agreement to abide by these rules. Winning is contingent upon fulfilling all requirements herein.

(14) Each Student Team must appoint a "Team Captain" to carry out all correspondence regarding the Student Team's entry. The Team Captain must be a citizen or permanent resident of the United States.

### **Submission Requirements:**

1. Each Student Team may submit only one entry into this challenge through the Team Captain. The Team Captain will submit a Student Team's entry on behalf of the Student Team by following the links and instructions at <http://venturewell.org/students/debut/guidelines> and certify that the entry meets all the challenge rules. At this time, teams will have the option to indicate that they wish to have their entries considered also for prizes sponsored by VentureWell. For a description of these prizes and rules of participation, see <http://venturewell.org/students/debut/guidelines>.
2. Each entry must comply with Section 508 standards that require federal agencies' electronic and information technology be accessible to people with disabilities, <http://www.section508.gov/>.
3. Each entry must be submitted as a single pdf file including the following 4 components:
  - i. The NIBIB DEBUT Challenge Certification Form (downloadable from <https://www.nibib.nih.gov/sites/default/files/NIBIB%20DEBUT%20Certificatio>



[n%20Form%202015.pdf](#) completed with project title and team member information, printed names, indication of U.S. citizenship or permanent residency, dates, and signatures of each individual member of the Student Team.

- ii. Project Narrative (not to exceed 6 pages using Arial font and a font size of at least 11 points) that includes the following 6 sections:
  - 1) Abstract
  - 2) Description of clinical need or problem, including background and current methods available. When the submitted entry is part of a bigger/ongoing project, the specific components designed and implemented by the competing Student Team must be clarified and distinguished from those accomplished by others (e.g. other students, advisor, collaborators).
  - 3) Project objective statement, describing the approach to address the problem, including a discussion of the innovative aspects
  - 4) Documentation of the design, providing sufficient detail
  - 5) Documentation of the prototype of the final design, with photographs, graphical representations, or link to a video, as appropriate.
  - 6) Proof that the design is functional and will solve the problem, providing a discussion of how the efficacy of the device was evaluated, including test results, graphics obtained with the designed solution and comparison to existing device outputs. A link to a 3-min video demonstrating the successful operation of the device developed is required. This link may be provided in this section, and will be requested separately during the online submission process.

The 6-page limit includes any graphics, but excludes the certification form, parental consent form, and any references. Submissions exceeding 6 pages for the Project Narrative will not be accepted.

Optional supporting material: The following optional supporting material may be submitted as a separate pdf file and will not count towards the 6-page limit: up to three support letters from stakeholders (patients, healthcare providers, industry, etc.); up to three supporting articles, reports, etc that present background information for your project; and up to 3 links to videos and/or websites.

However, the judges will mainly review the required components of your application and may consider the optional material at their discretion.

- iii. Sponsor letter, on department letterhead, from a faculty member from the Biomedical Engineering, Bioengineering or similar department of the institution in which the Student Team members are enrolled, verifying a) that the entry was achieved by the named Student Team, b) that each member of the team was enrolled full-time in an undergraduate curriculum during at least one semester or quarter of the academic year 2015-2016, and c) describing clearly any contribution from the advisor or any other individual outside the Student Team (especially when the submitted entry is part of a bigger/ongoing project, the specific components designed and implemented by the competing Student Team must be clarified and distinguished from those accomplished by others).
- iv. A completed [Parental Consent Form](https://www.nibib.nih.gov/sites/default/files/Parental%20Consent%20Form.pdf), downloadable from <https://www.nibib.nih.gov/sites/default/files/Parental%20Consent%20Form.pdf>, for each individual on the Student Team who is under the age of 18.

**Amount of the Prize; Award Approving Official:** The 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> place prizes will be \$20,000, \$15,000, and \$10,000, respectively, to be distributed only among the members of the winning Student Team eligible to win a prize in this challenge. The prize will be distributed equally among the prize-eligible Student Team members, i.e., students who are either citizens or permanent residents of the United States. Each prize-eligible member of the winning Student Teams must provide his/her bank information to enable electronic transfer of funds. Five honorable mentions will also be awarded, without an accompanying monetary prize.

Winning Student Teams will be honored at the NIBIB DEBUT Award Ceremony during the 2016 Annual Meeting of the Biomedical Engineering Society (BMES) in Minneapolis, Minnesota in October 2016. Updated information on the BMES annual meeting can be found at <http://bmes.org/annualmeeting>. NIBIB will not provide financial support for winning Student Teams or Honorable Mention awardees to attend the award ceremony. However they are welcome and encouraged to attend the award ceremony, or designate a representative to attend on their behalf. NIBIB reserves the right to cancel, suspend, modify the challenge, and/or not award a prize if no entries are deemed worthy. The NIBIB prize-approving official will be the Director of NIBIB.

**Payment of the Prize:** Prizes awarded under this Challenge will be paid by electronic funds transfer and may be subject to Federal income taxes. HHS/NIH will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Basis upon Which Winner Will Be Selected: The winning entries will be selected based on the following criteria:

- Significance of the problem addressed— Does the entry address an important problem or a critical barrier to progress in clinical care or research?
- Impact on potential users and clinical care—How likely is it that the entry will exert a sustained, powerful influence on the problem and medical field addressed?
- Innovative design (creativity and originality of concept)—Does the entry utilize novel theoretical concepts, approaches or methodologies, or instrumentation?
- Working prototype that implements the design concept and produces targeted results—Has evidence been provided (in the form of results, graphs, photographs, films, etc.) that a working prototype has been achieved?

Additional Information: For more information and to submit entries, visit

<http://www.nibib.nih.gov/training-careers/undergraduate-graduate/design-biomedical-undergraduate-teams-debut-challenge/> or <http://venturewell.org/students/debut>.

Dated: September 30, 2015

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Jeffrey D. Domanski

Executive Officer

National Institute of Biomedical Imaging and Bioengineering

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